081731,449



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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | AT | ATTY, DOCKET NO. | |
| 08/731, | ,499 10/ | 16/96 GRAY | J | 2500.124051 | |
| | | - | EXAMINER | | |
| 020227 | | HM22/0913 | | | |
| MAJESTI SUITE : | | SIEBERT & HSUE | JAHNSON | PAPER NUMBER | |
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| SAN FRA | ANCISCO CA | 94111-4106 | 1642 | | |
| | | | DATE MAILED: | 89/13/99 | |

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| | DATE MAILED: | |
| | <i></i> | 09/13/99 |
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| This is a communication from the examiner in charge of your application. | | |
| COMMISSIONER OF PATENTS AND TRADEMARKS | | |
| OFFICE ACTION SUMMARY | | |
| OFFICE ACTION SUMMANY | | |
| M- (120190 - 0 4127199 | } | |
| Responsive to communication(s) filed on 6/29/99 and 4/27/99 | (| |
| ☐ This action is FINAL. | | |
| | | |
| Since this application is in condition for allowance except for formal matters, prosecution as | to the merits is o | closed in |
| accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213. | | • |
| A shortened statutory period for response to this action is set to expire | month(s), or this | tv davs. |
| whichever is longer, from the mailing date of this communication. Failure to respond within the p | eriod for response | will cause |
| the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained u | nder the provision | s of 37 CFR |
| 1.136(a). | | |
| Disposition of Claims | | |
| | | |
| X Claim(s) -1-40 | is/are pending | in the application. |
| Of the above, claim(s) 24-44 | is/are withdrawn | rom consideration. |
| Claim(s) | i: | s/are allowed. |
| X Claim(s) 1-23 45-46 | i | s/are rejected. |
| Claim(s) | | re objected to. |
| Claim(s) are subject | | • |
| | | • |
| Application Papers | | |
| | | |
| See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. | | |
| The drawing(s) filed onis/are objected to b | | |
| The proposed drawing correction, filed on | is approved | disapproved. |
| The specification is objected to by the Examiner. | | |
| The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. § 119 | | |
| Thomas and a discovery the | | |
| Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). | | |
| ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have b | aon. | |
| ☐ All ☐ Some- ☐ None of the CERTIFIED copies of the priority documents have b | ce ii | |
| received. | | |
| received in Application No. (Series Code/Serial Number) | | |
| received in this national stage application from the International Bureau (PCT Rule 17.2 | !(a)). | |
| | · · · · · · · · · · · · · · · · · · · | |
| *Certified copies not received: | | · |
| A classical desired in mode of a plain for demantic minimum des 25 U.S.C. § 110(a) | | |
| Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e). | | |
| Attachment(s) | | |
| | | |
| Notice of Reference Cited, PTO-892 2 ft 2 | | |
| Information Displayure Statement(s), DTC 4440, Do-se Ma(s) | | |
| Information Disclosure Statement(s), PTO-1449, Paper No(s). | | |
| Interview Summary, PTO-413 | | |
| Notice of Draftperson's Patent Drawing Review, PTO-948 (1) | | |
| | | |
| Notice of Informal Patent Application, PTO-152 | | |
| -SEE OFFICE ACTION ON THE FOLLOWING PAGE | } | |

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1. Please note that the Examiner assigned to your application in the PTO has changed.

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2. The Restriction Requirements of Paper #14, mailed 2/17/98 and Paper #21, mailed 2/19/99 are withdrawn. The original Restriction requirement of Paper #12, mailed 11/12/97 is reinstated and maintained. Applicant's election with traverse of Group I (claims 1-23 and 45-46) is reiterated. For reasons already of record, in Paper #, mailed //9, the requirement is still deemed proper and is therefore made FINAL.

Regarding the restriction requirement and withdrawn of the claims of Group II (claims 24-38, 42), the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable.

3. Claim 46 has been added.

Claims 1-46 are pending.

Claims 24-44, drawn to non-elected inventions, are withdrawn from examination.

Claims 1-23 and 45-46 are examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Literal support is not found in the specification for the recitation "said nucleic acid has a length of at least 50 nucleotides" and it is considered to be new matter.

6. Claims 1-23 and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "specifically hybridizes" in claims 1, 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 is vague and indefinite. The properties that the recitation "specifically" impart to the claimed hybridizing nucleic acids is unclear.

The recitation "stringent conditions" in claims 1, 2, 6, 8, 10, 12, 14, 16, 18 and 20 is vague and indefinite. Absent limitations directed setting forth specific stringency conditions (temperature and salt concentration), the metes and bounds of nucleic acid sequences hybridizing under "stringent conditions" is unknown.

The recitation "the subsequence" in claims 3, 4, 6-17 and 20-21 lacks proper antecedent basis.

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The recitation "subsequence" in claims 3, 4, 6-17 and 20-21 is vague and indefinite. It is unclear what qualifies as a "subsequence."

- 7. The rejection of claims 1, 18 and 19 under 35 U.S.C. 112, first paragraph, in Paper #17, mailed 6/9/98, because the specification does not reasonably provide enablement for the scope of the claims, is withdrawn.
- 8. Claims 1-2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 23 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1994-1995 Promega Catalog. Page 167 discloses dNTPs that are the same as the claimed nucleic acid molecules, capable of hybridizing to any of SEQ ID NO:2-10 and 12.
- 9. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by the 1993/94 New England Biolabs Catalog. Pages 152-153 discloses promoter sequences operably linked to the polynucleotide sequences of claim 1 (single nucleotide residues), and thus, are the same as that claimed.
- 10. Claims 1, 6, 22-23, 45-46 are rejected under 35 U.S.C. 102(a) as being anticipated by any of Accession Numbers N32481 (10 Jan 1996), N93893 (05 April 1996) or G11697 (19 Oct

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1995). All disclose nucleic acids that would hybridize to SEQ ID NO:4 and are the same as that claimed.

- 11. Claims 1,8, 22-23 and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Accession Numbers H16953 (29 June 1995), 16954 (29 June 1995) or H12950 (27 June 1995). All disclose nucleic acid sequences that would hybridize to SEQ ID NO:5 and are the same as that claimed
- 12. Claims 1, 10, 22-23 and 45-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession Number H40682 (16 Aug 1995). Disclosed is a nucleic acid that would hybridize to SEQ ID NO:6 and is the same as that claimed.
- 13. Claims 1, 12, 22-23 and 45-46 are rejected under 35 U.S.C. 102(a) as being anticipated by either of Accession Number G27410 (28 June 1996) or G25553 (31 May 1996). Both disclose a nucleic acid that would hybridize to SEQ ID NO:7 and are the same as that claimed.
- 14. Claims 1, 14, 22-23, 45-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession Number N78571 (29 March 1996). Disclosed is a nucleic acid that would hybridize to SEQ ID NO:8 and is the same as that claimed.

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15. Claims 1, 16, 18, 22-23, 45-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession Number N70546 (14 march 1996). Disclosed is a nucleic acid that would hybridize to wither of SEQ ID NO:9 or SEQ ID NO:10 and is the same as that claimed.

- 16. The rejection of claims 1, 18, 22-23 45-46 under 35 U.S.C. 102(a) as being anticipated by Accession Number WO5407 is made and maintained. Disclosed is a nucleic acid that would hybridize to SEQ ID NO:10 and is the same as that claimed.
- 17. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 18. Claims 3, 5, 7, 9, 11, 13 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of prior U.S. Patent No. 5,892,010. This is a double patenting rejection.
- 19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 20. Claims 1-2, 4, 6, 8, 10, 12, 16, 18, 20, 22-23, 44-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,892,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are drawn to the same inventive concept, nucleic acid sequences comprising the sequences of any of SEQ ID NO:2-7.
- 21. Claims 1-23 and 44-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over non-elected claims 1-21 and 25-29 of copending Application No. 08/785,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because all are drawn to the same inventive concept, nucleic acid sequences comprising the sequences of any of SEQ ID NO:2-10 and 12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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22. Any inquiry concerning this communication or earlier communications from the examiner

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should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner

can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may

be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any

inquiry of a general nature or relating to the status of this application or proceeding should be

directed to the Group receptionist whose telephone number is (703) 308-0196.

Nancy A Johnson Primary Examiner

September 12, 1999